AUG 2 8 2001

SECTION D **510(k) SUMMARY**

510(k) Number: K011905

Trade Name: *Sniper Elite*™ Hydrophilic Guide Wire

Common Name: Guidewire

Classification Name: Catheter Guidewire (per CFR 21 Part 870.1330, 74 DQX)

Product Code: DQX

Classification: Class II

Submitted by:
Maxxim Medical
1445 Flat Creek Rd.
Athens, TX 75751
Phone: 903-675-9321
Fax: 903-677-9397

Contact person: Gail Doherty, Compliance Manager

Date prepared: 6/18/01

Legally marketed devices to which equivalence is claimed:

Maxxim Medical Heparin Coated Stainless Steel/Teflon Coated Spring Guidewire, K832030

Description of Device:

The *Sniper Elite*™ Hydrophilic Guidewire is constructed from a super elastic, Nitinol core wire. A plastic cladding is applied over the Nitinol core, with a hydrophilic coating covering the plastic cladding. The polymer cladding is impregnated with a radiopacive agent and a platinum/8% tungsten coil is located in the distal tip for enhanced contrast under fluoroscopy.

Scientific concepts that form the basis for the device:

This guide wire has a core made from Nitinol, a metal that has a high resistance to kinking. The Nitinol core is cladded with a polymer of low enough durometer not to inhibit the super-elastic properties of Nitinol. The plastic cladding is coated with a durable hydrophilic coating, to provide a low friction surface when wet. The radiopacive agent that is impregnated in the polymer cladding and a platinum/8% tungsten coil in the distal tip provide enhanced radiopacity, when imaged under fluoroscopy. The hydrophilic coating is more lubricous distally than proximally to promote increased handling characteristics. The guidewire tip is color coded to indicate the size of the wire.

Intended Use of Device:

Sniper Elite™ Hydrophilic Guidewires are designed for use in angiographic procedures to introduce/position catheters and interventional devices within the vasculature.

Comparison of Fundamental Scientific Technology to legally marketed device:

The *Sniper Elite*™ Hydrophilic Guidewire is being compared to the Maxxim Medical Heparinized, Teflon Coated Spring Guidewire.

The predicate device has:

1) An internal core that is tapered distally for increased tip softness, as does the *Sniper Elite*™ Hydrophilic Guidewires.
2) A stainless steel coil covering the core that extends the length of the wire, while the *Sniper Elite*™ possesses a polymer cladding that also extends the length of the wire, which incorporates the distal radiopaque coil. The function of the stainless steel coil and the cladding are to retain a consistent outer dimension for the wire and provide radiopacity, while retaining the flexibility imparted to the wire by the core wire.
3) A Heparinized-Teflon coating and the *Sniper Elite*™ has a hydrophilic coating for increased lubricity through the vasculature.

Performance Data:

Testing was conducted in accordance with the FDA's Coronary and Cerebrovasculature Guidewire Guidance (FDA document #964, 1-1995) and the ISO Standard 11070, Sterile single-use intravascular catheter introducers (1998-5-1, guide wire section). The following tests demonstrated substantial equivalence:

- Lubricity
- Coating Adherence
- Torque Strength
- Torqueablility
- Tip Softness
- Tip Flexibility

- Tensile Strength
- Fracture Test
- Kink Resistance
- Radiopacity
- Catheter Compatibility

Test results demonstrate that the *Sniper Elite*™ Hydrophilic Guidewire is substantially equivalent to the Maxxim Medical Heparinized, Teflon Coated Spring Guidewire.

Packaging and Sterilization Information

Maxxim Medical packages the Maxxim Medical Heparinized Teflon Coated Spring Guidewire (enclosed in dispenser) in a single put-up pouch and sterilized. The Spring Guidewire is packaged in a Tyvek pouch, 10 pouches to a shelf carton as the typical packaging configuration. Sterilization for Maxxim Medical is by a validated ethylene oxide sterilization (EtO) method that is referenced in ANSI/AAMI/ISO 11135-1994 "MEDICAL DEVICES- Revalidation and Routine Control of Ethylene Oxide Sterilization." The packaging and sterilization of the *Sniper Elite*™ will be identical to that for the predicate with a couple exceptions (torque handle included and 5 pouches/ shelf carton). The *Sniper Elite*™ is packaged with a torque handle (made by Maxxim Medical) in a Tyvek pouch, 5 pouches to a shelf carton and 10 shelf cartons in a shipper carton.

CONCLUSIONS:

Maxxim Medical concludes that the *Sniper Elite*™ Hydrophilic Guidewires are substantially equivalent to the Maxxim Medical Heparinized, Teflon Coated Spring Guidewire:

1) functionally and
2) with regards to safety and efficacy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Gail Doherty
Manager
Maxxim Medical
1445 Flat Creek Rd.
Athens, TX 75751

Re: K011905
Sniper Elite Model-Or-E3872XX Series
Regulation Number: 870.1330
Regulatory Class: II
Product Code: DQX
Dated: July 24, 2001
Received: August 2, 2001

Dear Ms. Doherty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011905

Device Name: **Sniper Elite Hydrophilic Guidewire**

Indications For Use:

Sniper Elite Hydrophilic Guidewires are designed for use in angiographic procedures to introduce/position catheters and interventional devices within the vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011905

(Optional Format 3-10-98)